# JCTLM Reference Materials Template: Examples

Analyte/Paran	neter	Basis for Tra	aceability	Mar	trix	RM			C	Concentration Range Certified/A	of Analyte	e	Range of Ex	panded Un rtified/Assi	certainty for a	Analyte	Information for Assessing Commutability					Congruent with other critical factors in ISO 15194 (list other relevant factors)?								
Analyte Category	Analyte Name	Traceable de to SI?	rocedurally- efined (if so, name/cite procedure	Matrix Category	Matrix	Identifier/ Number	Name		ode/approach used for value signment (if not clearly stated in certificate)	Comments	Issued by NMI wit Certificate			From	То	Unit	From	То	Unit		Physical form of RM matrix	RM fortified with analyte or naturally incurred	Applicable analy characteristics (e isoform(s); free/bound, tota	Other relevant factors (li	Citation of specifi st) publication/refere ce if available	Expression of Uncertainty				Additional Comments
electrolytes	sodium	yes		blood serum	human serum	SRM 909b	Human Serum	NIST		2 different materials	yes		yes	120.76	141.0	mmol/L	0.92	1.3	mmol/L	95	lyophilized	naturally- incurred				GUM Compliant				
electrolytes	sodium	yes		blood serum	human serum	SRM 956a	Electrolytes in Frozen Human Serum	NIST		3 different materials	yes		yes	121.4	160.9	mmol/L	0.3	0.4	mmol/L		frozen (liquid, ot lyophilized)	naturally- incurred matl & fortified matl				GUM Compliant				
electrolytes	sodium	yes		urine	human urine	SRM 2670	Toxic Metals in Freeze- Dried Urine	NIST		(SRM 2670a in progress)	yes		yes	2.62		mg/mL	5.3		% relative	95	lyophilized	naturally- incurred				GUM Compliant				
metabolites & substrates	cholesterol	yes		blood serum	human serum	SRM 909b	Human Serum	NIST		2 different materials	yes		yes	3.787	6.084	mmol/L	0.047	0.077	mmol/L	95	lyophilized	naturally- incurred	total			GUM Compliant				
metabolites & substrates	cholesterol	yes		blood serum	human serum	SRM 1951a	Lipids in Frozen Human Serum	NIST		2 different materials	yes		yes	4.7109 7	7.1554	mmol/L	0.0116	0.0142	mmol/L		frozen (liquid, not lyophilized)	naturally- incurred	total	Large scale study conducted vs fresh seru verified appropriateness material for major clinic meas. systems	of (Reference to be	GUM Compliant				
metabolites & substrates	cholesterol	yes		blood serum	human serum	SRM 968c	Fat-Soluble Vitamins, Carotenoids, and Cholesterol in Human Serum	NIST		2 different materials	yes		yes	3.454	4.318	mmol/L	0.035	0.043	mmol/L	95	lyophilized	naturally- incurred	total			GUM Compliant				
metabolites & substrates	cholesterol			high purity material	cholesterol	SRM 911b	Cholesterol	NIST			yes		yes	99.8	fr	mass fraction %	0.1		mass fraction %	95	neat solid					GUM Compliant				
drugs	THC-9-COOH	yes		urine	human urine	SRM 1511	Multi Drugs of Abuse in Freeze-Dried Urine	NIST			yes		yes	14.1		ng/mL	0.8		ng/mL	95	lyophilized	fortified			5 military field lab verified suitability Results in Certificate					
drugs	тнс-9-соон	yes		urine	human urine	SRM 1507b	11-Nor-Delta-9- Tetrahydrocannabinol-9- Carboxylic Acid in Freeze- Dried Urine	NIST		3 matis and urine blank	yes		yes	11.7	49.6	ng/mL	1.3	4.4	ng/mL	95	lyophilized	fortified				GUM Compliant			•	
non-electrolyte metals	lead	yes		whole blood	bovine blood	SRM 966	Toxic Metals in Bovine Blood	NIST		2 different materials	yes		yes	1.56	25.27	μg/dl	0.90	3.2	% relative		frozen (liquid, ot lyophilized)	naturally- incurred matl & fortified matl				GUM Compliant				
non-electrolyte metals	lead	yes		urine	human urine	SRM 2670	Toxic Metals in Freeze- Dried Urine	NIST		2 different materials (SRN 2670a in progress)	yes		yes	0.109	0.109	µg/ml	3.7	3.7	% relative	95	lyophilized	naturally- incurred matl & fortified matl				GUM Compliant				
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		Contact Inform	nation for Additional Details	Does RM value-assignment approach meet traceability	Additional Reviewer
Name	email address	phone number	How to obtain certificate	requirements of IVDD industry and regulatory community?	Comments
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/smcatalog/certificates/view_cert2gif.cfm?certificate=909b		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/smcatalog/certificates/view_cert/2gif.cfm?certificate=956a		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/srmcatalog/certificates/view_cert2gil.clm?certificate=2670		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/srmcatalog/certificates/view_cert2gif.cfm?certificate=909b_		
Willie May	willie.may@nist.gov	+301/975-3108	hap //patapaco.nist.gov/smcatalog/satificates/view_cerQqf_cfm?certificate=1961.s		
Willie May	willie.may@nist.gov	+301/975-3108	http://jpatapsco.nist.gov/srmcatalog/certificates/view_cert2gif.chm?certificate=968c		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/smcatalog/certificates/view_cert2gif.clm?certificate=911b		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/smcatalog/certificates/view_cert/2gif.dm?certificate=1611		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/smcatalog/certificates/view_cert2gif.cfm?certificate=1507b		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/smcatalog/common/view_detail.cfm?srm=966		
Willie May	willie.may@nist.gov	+301/975-3108	http://patapsco.nist.gov/smcatalog/certificates/view_cert2pif.cfm?certificate=2670		
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llowing are required for Pull-down Lists - DO NOT DELETE

non-electrolyte metals

	Matrix Categories		pression yes/no	
enzymes	calibration solution	95% CL	no	naturally-incurred
metabolites & substra	tt whole blood	99% CL		naturally-incurred matl & fortified
proteins	blood serum	s		
nucleic acids	blood plasma	other		
drugs	urine			
hormones (non-peptic	de other			
coagulation factor				
vitamins				

# JCTLM Reference Methods/Procedures: Examples

Analyte/Parameter	Method capable of traceability of	f	Matrix			Method/ F	rocedure				plicable M centration			hod Expa ertainty R					Congruent with other critical factors in ISO 75193 (list factors)?				factors)?		Contact Informati
Analyte Analyte Category Name	analyte to SI or defined procedure	? Matrix Category	Applicable Matrices	Identifier/ Number	Name	Organization that developed/validated method	Measurement Technique(s) Used	Comments 1	Comments 2	From	То	Unit	From	То	Unit	Peer Reviewed Publication	How to obtain copy of method literature publication is not available	if CCQM Key Comparison Report	Non-CCQM Interlab Comp. Report					Additional Comments	Name
metabolites & glucose substrates	SI	blood serun	lyophilized, fresh, or frozen serum		NIST definitive Method for Serum Glucose	NIST	ID/GC/MS	butylboronate acetate derivation	Calilbrate with SRM 917b, High Purity Glucose	2	20	mmol/L	0.5	1.5	% relative	Biomed Mass Spectrom 9, 395-405 (1982)		CCQM-K11							Willie May
metabolites & cholesterol	SI	blood serun	lyophilized, n fresh, or frozen serum		NIST definitive Method for Serum Cholesterol	NIST	ID/GC/MS	trimethylsilyl derative	Calibrate with SRM 911b, high purity cholesterol	2	10	mmol/L	0.5	1	% relative	Anal Chem 61, 1718-1723 (1989)		CCQM-K6; http://www.bipm.org/pdf/final_reports/QM/K6/CCQM-K6.pdf							Willie May
enzymes GGT	procedurally-define	d blood serun	lyophilized, fresh, or frozen human serum or plasma		IFCC Refereence Method	IFCC Reference Method for Enzymes at 37C	Spectrophotometric	Reaction at pH 7.7		change in abs.>0.2 /min	U/I							IRMM/IFCC 452						G. Schumann	schumann.gerhard@mh-hannover.de
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on for Additional Det	ails	Does Ref. Method value- assignment approach meet traceability	Additional Reviewer Comments
email address	phone number	requirements of IVDD industry and regulatory community?	Additional Notice Commons
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Following are required	for Pull-down Lists - D	O NOT DE	LETE
Analyte Categories	Matrix Categories	yes/no	_
electrolytes	high purity material	yes	SI

enzymes calibration solution no procedurally-defined

metabolites & substrate whole blood

proteins blood serum

nucleic acids blood plasma drugs urine

hormones (non-peptide other coagulation factor vitamins non-electrolyte metals other

JCTLM Reference Materials Nominations Template
To enable sorting, etc., please: 1) complete one line for each analyte-RM combination 2) do not merge cells within the table, just copy cells as appropriate if there are multiple analytes with assigned values in an RN

Analyte/Para	meter	Basis for Traceability Matrix		RM			Concent	ration or Con Range of Anal fied/Assigned	centration yte Range of Expanded Uncertainty for Analyte Certified/Assigned Value	Information for Assessing Commutability Congruent with other critical factors in ISO 15194 (list other relevant factors)?					
							Certi	fied/Assigned	Value Certified/Assigned Value						
Analyte Category	Analyte Name	Traceable defined (if so, name/cite procedure)  Matrix Category Matrix  Matrix Category Matrix	Identifier/ Number Name	Certifying Organization Mode/approach used for value assignment (if not clearly stated in certificate)	Comments	Issued by NMI with Certificate from Other RM Database?	From	То	Unit From To Unit Lev. of Physical form of RM matrix	RM fortified with analyte or naturally incurred	Applicable analyte characteristics (e.g., isoform(s); free/bound, total)  Other relevant factors (list)	Citation of specific publication/referen ce if available Expression of Uncertainty			Additional Comments
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Following are required for Pull-down Lists - DO NOT DELETE

Analyte Categories Matrix Categories Uncertainty Expressior yes/no enzymes calibration solution 95% CL no naturally-incurred

metabolites & substrate whole blood 99% CL naturally-incurred matl & fortified matl

proteins blood serum nucleic acids blood plasma drugs urine hormones (non-peptids other coagulation factor vitamins non-electrolyte metals other s other

JCTLM Reference Methods/Procedures Nominations Template
To enable sorting, etc., please: 1) complete one line for each analyte-method combination 2) do not merge cells within the table, just copy cells as appropriate if there are multiple analytes with assigned values in an RN

Analyte/Pa	rameter	Method capable of	Matrix		Method	V Procedure			Applicable Method Concentration Range	Method Expanded Uncertainty Range Method/Procedu					Method/Procedure Documentation Congruent with other critical factors in ISO				ers in ISO 75	5193 (list fac	ctors)?	Contact Informati	
		traceability of																		Additional Comments			
Analyte Category	Analyte Name	defined procedure?  Matrix Category	Applicable Matrices	Identifier/ Number	Organization that developed/validated method	Measurement Technique(s) Used	Comments 1	Comments 2	From To Unit	From	То	Unit Pe	eer Reviewed Publication	How to obtain copy of method it literature publication is not available	CCQM Key Comparison Report	Non-CCQM Interlab Comp. Report						Name	
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Following are required for Pull-down Lists - DO NOT DELETE

Analyte Categories Matrix Categories yes/no
electrolytes high purity material yes SI

calibration solution no procedurally-defined

metabolites & substrats whole blood proteins blood serum nucleic acids blood plasma drugs urine hormones (non-petate other coagulation factor vitamins non-electrolyte metals other